Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Joseph I. Boullata, Pharm.D., BCNSP, FACN, FASPEN
Pharmacy Specialist in Nutrition Support, Hospital of the University of Pennsylvania
Clinical Professor, Department of Nutrition Sciences, Drexel University
Philadelphia, Pennsylvania

Phil Ayers, Pharm.D., BCNSP, FASHP
Chief, Clinical Pharmacy Services, Baptist Medical Center
Associate Clinical Professor, University of Mississippi School of Pharmacy
Jackson, Mississippi

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Learning Objectives

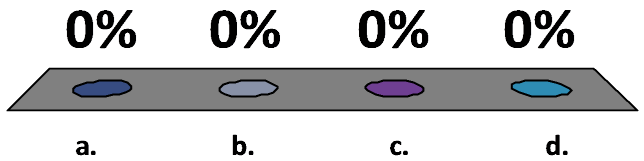
- Examine the current state of malnutrition in hospitalized patients.
- Identify best practices for the appropriate use and safe delivery of parenteral nutrition.
- Using a clinical case study, illustrate safe and appropriate use of parenteral nutrition in an acutely ill patient.
- Using a clinical case study, illustrate considerations for the safe and appropriate use of long-term parenteral nutrition therapy.

Assessing the Nutrition Status of Patients in the Hospital Setting

Phil Ayers, Pharm.D., BCNSP, FASHP
Chief, Clinical Pharmacy Services
Baptist Health Systems
Associate Clinical Professor
University of Mississippi School of Pharmacy
Jackson, Mississippi

Which of the following is the most accurate nutritional marker ?

a. Prealbumin
b. Albumin
c. Transferrin
d. None of the above



HCUP Malnutrition Facts

- In 2013, the all-cause 30-day readmission rate for patients with malnutrition 23/100, compared with 14.9/100 for patients without malnutrition
- For all types of malnutrition combined, the rate of readmission was highest among
  - Ages 18-64 years
  - Medicaid patients
  - Patients in metropolitan areas

Statistical Brief 210. National Inpatient Sample (NIS), 2013. Healthcare Cost and Utilization Project (HCUP). Agency for Healthcare Research and Quality (AHRQ); Sep 2016. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp (accessed 2017 Oct 25).

HCUP Malnutrition Facts, 2013

- Average cost/readmission was $16,900 for patients with protein-calorie malnutrition and $17,900 for patients with post-surgical non-absorption versus $13,400 readmission cost for patients without malnutrition

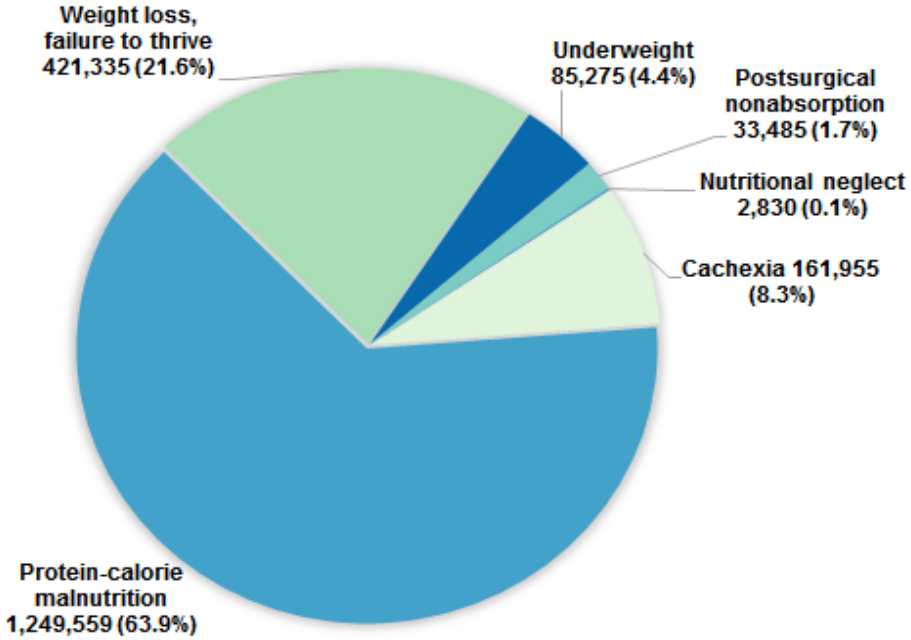
Statistical Brief 210. National Inpatient Sample (NIS), 2013. HCUP; Sep 2016. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp (accessed 2017 Oct 25).

HCUP Malnutrition Facts, 2013

- Septicemia was the leading diagnosis at readmission involving all types of malnutrition, except post-surgical non-absorption for which complication of device (implant or graft) was the leading reason for readmission

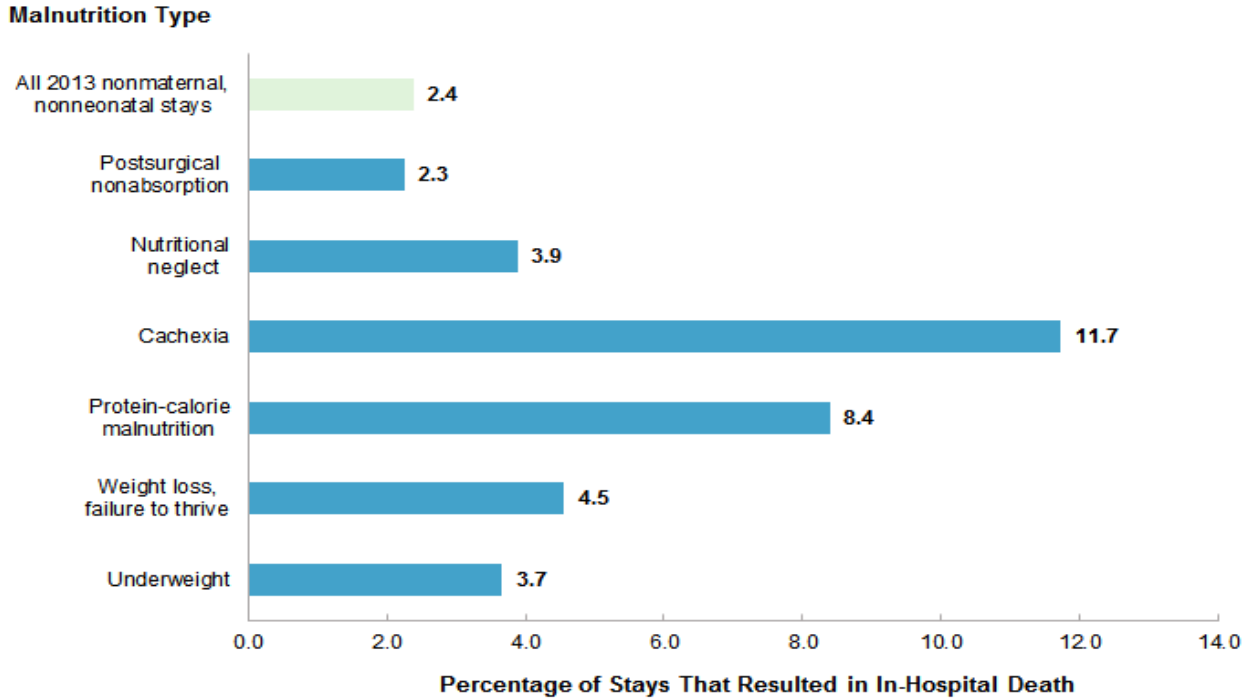
Statistical Brief 210. National Inpatient Sample (NIS), 2013. HCUP; Sep 2016. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp (accessed 2017 Oct 25).

Types of Malnutrition among Hospital Stays with Malnutrition, 2013



Statistical Brief 210. National Inpatient Sample (NIS), 2013. HCUP; Sep 2016. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp (accessed 2017 Oct 25).

In-hospital Death by Malnutrition Type, 2013



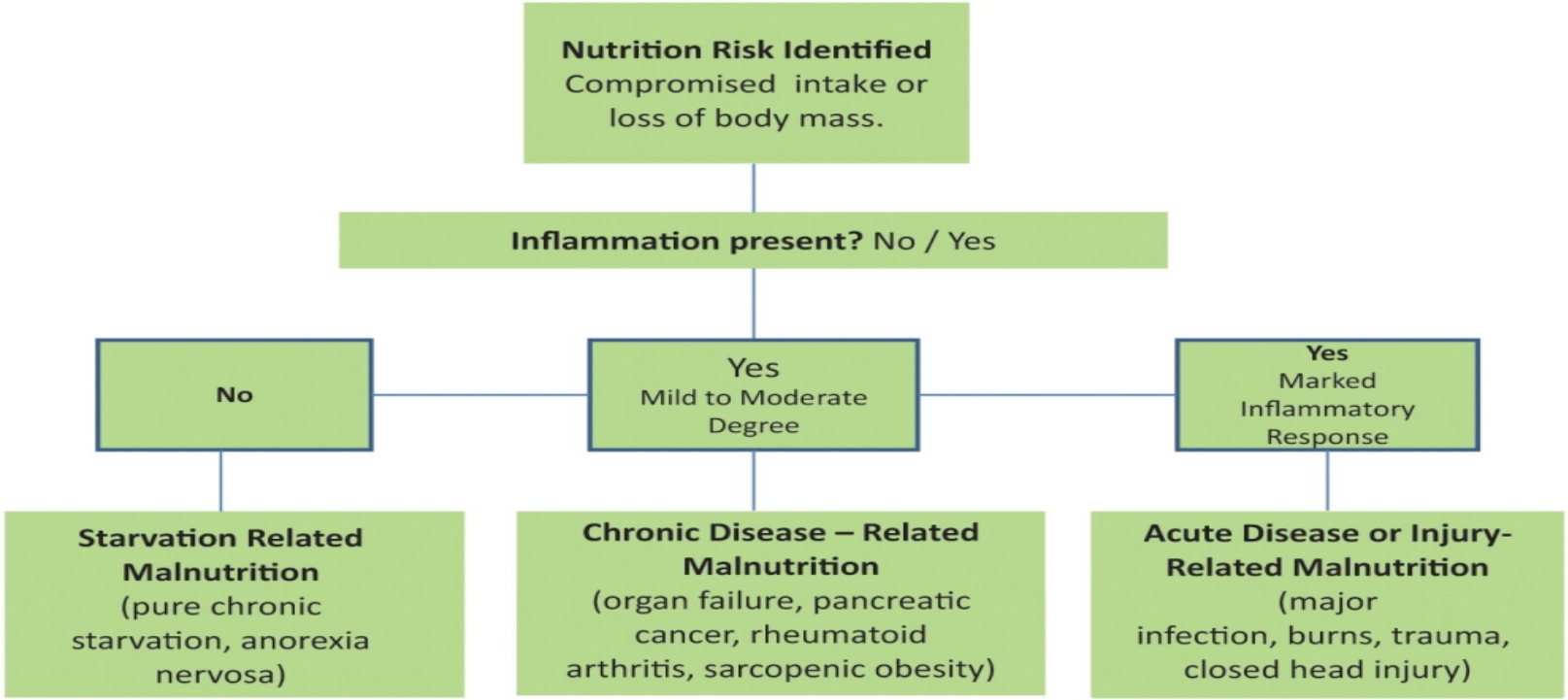
Statistical Brief 210. National Inpatient Sample (NIS), 2013. HCUP; Sep 2016. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp (accessed 2017 Oct 25).

Nutrition Disorders and Nutrition-Related Conditions

- Malnutrition/undernutrition
- Sarcopenia and frailty
- Overweight and obesity
- Micronutrient abnormalities
- Re-feeding syndrome

Cederholm T et al. *Clin Nutr*. 2017; 36:49-64.

Etiology-based Malnutrition Definitions



Adapted from Jensen GL et al. Malnutrition syndromes: a conundrum vs continuum. *JPEN J Parenter Enteral Nutr*. 2009; 33:710. With permission from American Society for Parenteral and Enteral Nutrition (ASPEN).

AND/ASPEN Clinical Characteristics to Support Diagnosis of Malnutrition

- Energy intake
- Interpretation of weight loss
- Body fat
- Muscle mass
- Fluid accumulation
- Reduced grip strength

AND = Academy of Nutrition and Dietetics

White JV et al. *JPEN J Parenter Enteral Nutr*. 2012; 36:275-83.

Body Composition and Lab Studies

- Anthropometrics
- Bioelectrical impedance (BIA)
- Dual energy X-ray absorptiometry (DEXA)
- Imaging with CT or MRI
- Ultrasound
- Laboratory studies
  - Visceral proteins: albumin, prealbumin, transferrin, retinol binding protein, C-reactive protein
  - Nitrogen balance
  - Urine 3-methylhistidine

Mueller CM. ASPEN Adult Nutrition Support Core Curriculum, 2012.

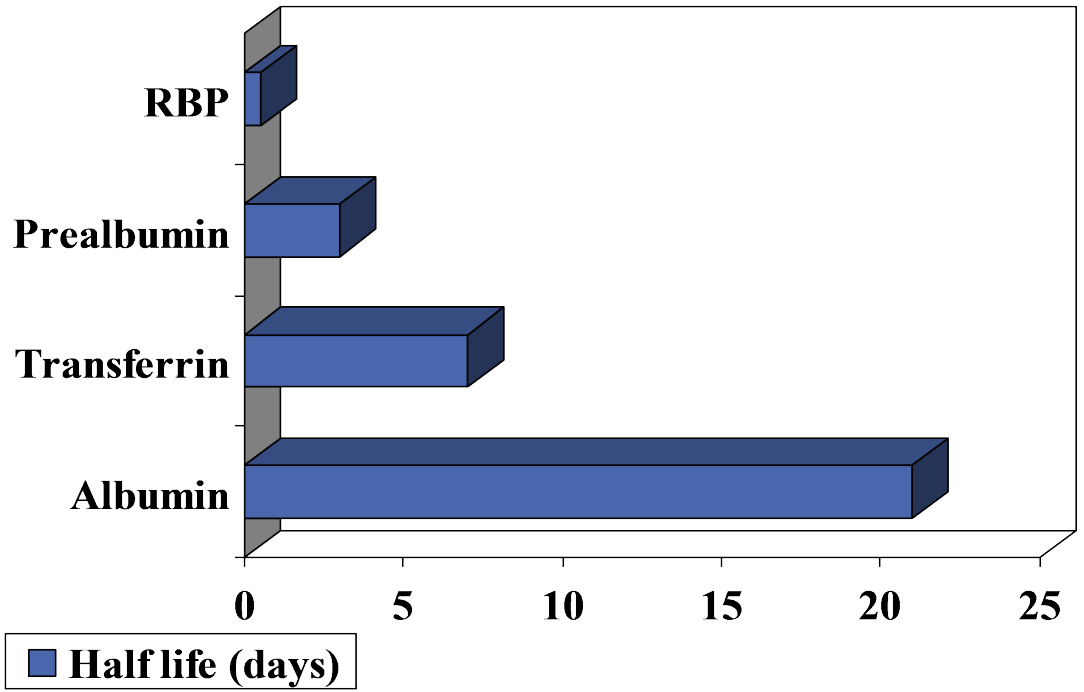
Obesity Classification and Risk

Obesity Class	BMI, kg/m^2
Underweight	< 18.5
Normal	18.5-24.9
Overweight	25-29.9
Obesity class I	30-34.9
Obesity class II	35-39.9
Obesity class III	≥ 40
High risk	Waist circumference, cm Men > 102, Women > 88

BMI = body mass index

NIH publication no. 98-4083, September 1998.

Visceral Protein Compartment



Nutritionally-at-Risk Adults

- Involuntary loss of 10% or more of usual body weight within 6 months or involuntary loss of ≥ 5% or more of usual body weight in 1 month
- Involuntary loss or gain of 10 lb within 6 months

ASPEN. Definitions of terms – 2015. https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Toolkits/Malnutrition_Toolkit/Definitions/ (accessed 2017 Nov 8).

Nutritionally-at-Risk Adults

- BMI < 18.5 kg/m^2 or > 25 kg/m^2
- Chronic disease
- Increased metabolic requirements
- Altered diets or diet schedules
- Inadequate nutrition intake, including not receiving food or nutrition products for greater than 7 days

ASPEN. Definitions of terms – 2015. https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Toolkits/Malnutrition_Toolkit/Definitions/ (accessed 2017 Nov 8).

Nutritionally-at-Risk Children

- A weight for length or weight for height < 10th percentile or > 95th percentile
- BMI for age or sex < 5th percentile or > 85th percentile
- Increased metabolic requirements

ASPEN. Definitions of terms – 2015. https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Toolkits/Malnutrition_Toolkit/Definitions/ (accessed 2017 Nov 8).

Nutritionally-at-Risk Children

- Impaired ability to ingest or tolerate oral feedings
- Documented inadequate provision or tolerance of nutrients
- Inadequate weight gain or a significant decrease in usual growth percentile

ASPEN. Definitions of terms – 2015. https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Toolkits/Malnutrition_Toolkit/Definitions/ (accessed 2017 Nov 8).

Nutritionally-at-Risk Neonates

- Low birth weight (<2500 g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders
- Birth weight > 2 standard deviations below the mean for gestational age on fetal weight curves
- Acute weight loss of 10% or more

ASPEN. Definitions of terms – 2015. https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Toolkits/Malnutrition_Toolkit/Definitions/ (accessed 2017 Nov 8).

Nutrition Assessment Tools

Assessment Tool	Parameters	Illness Severity	Other Variables
Mini nutritional assessment	Weight, height, mid-arm and calf circumferences, diet history, appetite, feeding mode	Albumin, prealbumin, cholesterol, lymphocyte count	Self-perception of nutrition and health status
Subjective global assessment	Weight history, diet history	Primary diagnosis, stress level	Physical symptoms (SC fat, muscle wasting, ankle and sacral edema, functional capacity, GI symptoms)
NRS 2002	Weight loss, BMI, food intake	Stress level	
NUTRIC Score	Age, days in hospital to ICU admission	APACHE II, SOFA score, number of comorbidities, IL-6	

Mueller C et al. *JPEN J Parenter Enteral Nutr*. 2011; 35:16-24.

NRS 2002 and NUTRIC Score

Impaired Nutritional Status		Severity of Disease	
Absent Score 0	Normal nutritional status	**Absent Score 0**	Normal nutritional requirements
Mild Score 1	Wt loss > 5% in 3 mos Or Food intake below 50-75% of normal requirement in preceding week	**Mild Score 1**	Hip fracture Chronic patients in particular with acute complications: cirrhosis, COPD *Chronic hemodialysis, diabetes, oncology*
Moderate Score 2	Wt loss > 5% in 2 mos Or BMI 18.5–20.5 + impaired general condition Or Food intake 25-50% of normal requirement in preceding week	**Moderate Score 2**	Major abdominal surgery, Stroke *Severe pneumonia, hematologic malignancy*
Severe Score 3	Wt loss > 5% in 1 month (15% in 3 mos) Or BMI <18.5 + impaired general condition Or Food intake < 25% of normal requirement in preceding week	**Severe Score 3**	Head injury Bone marrow transplantation *Intensive care patients (APACHE II ≥ 10)*

Note: If age ≥ 70 years, add 1 point Disease states in italics are based on clinical judgement.
Total score = (Points for nutritional status) + (Points for disease severity) + (Points for age)

NRS 2002 Score

- Score ≥ 3: enteral or parenteral nutrition should be considered
- Score ≥ 5: High nutritional risk

NUTRIC Score

- Score ≥ 6: High nutritional risk

Factors	NUTRIC Points			
	0	**1**	**2**	**3**
Age (yrs)	<50	50-74	≥ 75	-
APACHE II Score	<15	15-19	20-27	≥ 28
Baseline SOFA Score	<6	6-9	≥ 10	-
# Comorbidities	0-1	≥ 2	-	-
Days in hospital to ICU admit	0	≥ 1	-	-
Interleukin-6 (μ/ml)	0-399	≥ 400	-	-

Total Score = (Total from six separate factors)

Applying Best Practices to Ensure Safe and Appropriate Use of Parenteral Nutrition

Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN
Pharmacy Specialist in Nutrition Support
Clinical Nutrition Support Services
Hospital of the University of Pennsylvania
Clinical Professor, Department of Nutrition Sciences
Drexel University
Philadelphia, Pennsylvania

Outline

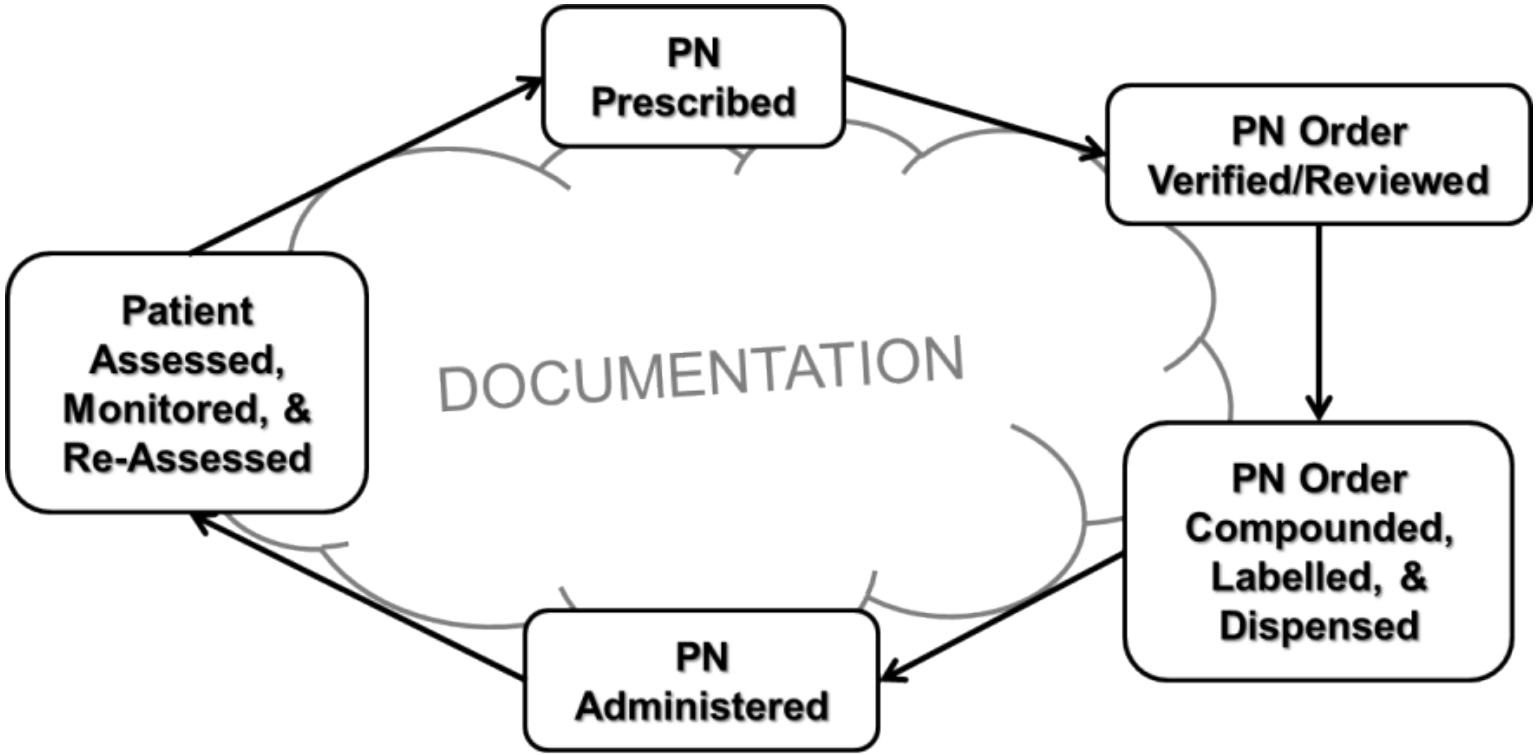
- Introduction
- Indication
- Route and Timing
- Dosing and Formulation
- Preparation
- Barriers to Successful PN Therapy

Introduction

Parenteral Nutrition (PN)

- Valuable therapeutic intervention
  - Variety of practice settings and patient populations
- Most complex prescription drug
  - High-alert medication
  - Medication safety officer awareness
- PN-use process
  - Involves several departments and clinicians

PN-Use Process



Pharmacist Needs Assessment

- Malnutrition is prevalent
- Inadequate education and training
- Awareness of the wide array of PN products
- Applying pharmaceutics to clinical practice
- Management varies considerably from best practices

Guidance Documents

- Sterile products
  - American Society of Health-System Pharmacists
    - Technical assistance bulletins
    - Guidelines (compounding; use of automated compounding device; outsourcing)
  - United States Pharmacopeia (USP)
    - National Coordinating Committee for Large Volume Parenterals
    - USP Chapter <797>
  - Institute for Safe Medication Practices
    - Guidelines for safe preparation of sterile compounds

Guidance Documents

- PN-Specific
  - American Society for Parenteral & Enteral Nutrition (ASPEN)
    - Consensus recommendations
    - Clinical practice guidelines
    - Appropriateness of use recommendations
    - Standardized competencies
  - United States Pharmacopeia
    - USP Chapter <799>

Patient Information

Patient name_____Medical record number_____ Birthdate/age

_____ Patient location_____ Allergies_____

Height and dosing weight: Ht: ____cm Dosing Wt: _____kg

Diagnosis(es)/Indication(s) for PN_____

Vascular access device/location CVC type_____ Location_____

Administration date/time

Base Formula	Amount/day
Amino acids	g
Dextrose	g
IV Fat emulsion	g
Electrolytes	
Sodium phosphate	mmol
Sodium chloride	mEq
Sodium acetate	mEq
Potassium phosphate	mmol
Potassium chloride	mEq
Potassium acetate	mEq
Magnesium sulfate	mEq
Calcium gluconate	mEq
Vitamins, Trace Elements, Additives	
Multi-component vitamins	mL
Multi-component Trace elements	mL

Other Additives (eg, individual vitamins or trace elements, cysteine, regular insulin) as clinically appropriate and compatible

PN Instructions

Total volume_____mL Infusion rate_____mL/hr , start and stop times_____

Cycle information

Prescriber and contact information_____

Reprinted from Ayers P et al. A.S.P.E.N. parenteral nutrition safety consensus recommendations. *JPEN J Parenter Enteral Nutr*. 2014; 38:296-333. With permission from the American Society for Parenteral and Enteral Nutrition (ASPEN).

Adult / Pediatric / Neonatal
(Circle applicable patient population)

Case #_____

Pharmacist_____

Verified by_____

Date	Competency	Competency Met	Review Needed	Evaluator's Initials
	Verify PN order elements for:			
	Patient name and other identifiers			
	Birth date and or age			
	Allergies and associated manifestations			
	Height and dosing weight (metric units)			
	Diagnoses			
	Indication(s) for PN			
	Administration route and vascular access device			
	Prescriber contact information			
	Date and time the PN order was submitted			
	Administration date and time			
	Volume and infusion rate			
	Infusion schedule (continuous vs cyclic)			
	Rate of infusion tapered up/down if appropriate			
	Type of formulation (dextrose/amino acids or total nutrient admixture)			
	Verify PN ingredients for:			
	Amounts per day (adults); Amounts per kg per day (pediatrics, neonates)			
	Electrolyte ion doses as a salt form			
	A dose for each macronutrient			
	A dose for each electrolyte salt			
	A dose for fixed-dose multi-trace element product			
	A dose for individual trace element salt			
	A dose for fixed-dose multivitamin product			
	A dose for individual vitamins			
	A dose for insulin (if ordered)			
	A dose for other non-nutrient medications (if ordered)			
	Performs clinical review of the PN order for:			
	Indication consistent with published guidelines or scientific literature			
	Appropriate dose of each macronutrient for the patient given indication, body weight, organ function, and concurrent medications			
	Appropriate dose of each micronutrient for the patient given indication, body weight, organ function, and concurrent medications			
	Appropriate osmolarity for route of administration			
	Changes from previous PN order			
	Any prescriber over-ride to alerts generated by clinical decision support within a CPOE system are addressed			
	Performs pharmaceutical review of the PN order for:			
	Compatibility of all ingredients at ordered doses and volume			
	Stability of the final PN admixture at ordered doses and volume			
	Performs independent double-check for:			
	Transcription from PN order to pharmacy system			
	Transcription from PN order or pharmacy system to the ACD			
	Transcription of PN order to/from a pharmacy vendor			
	Any calculations or conversion of units-of-measure			
	Documents all steps as required for record keeping			

Adult / Pediatric / Neonatal
(Circle applicable patient population)

Case #_____

Pharmacist / Pharmacy Technician_____

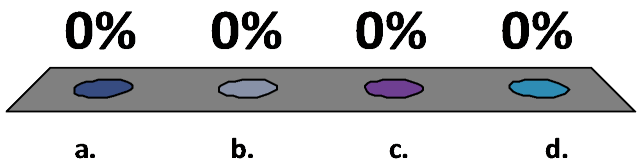
Verified by_____

Date	Competency	Competency Met	Review Needed	Evaluator's Initials
	Automated Compounding Device			
	Uses vendor-validated setup			
	Includes a second staff member for initial setup • Uses independent double-check • Uses printed check • Verbally affirms all components including name, concentration, container size			
	Uses barcode technology to verify products during initial setup			
	Uses barcode technology to verify products during replacement of each ingredient			
	Traces tubing from the source container to the port attached to the ACD during initial setup			
	Traces tubing from the source container to the port attached to the ACD during replacement of each source container			
	Requests independent pharmacist or supervisor verification when multiple source containers of a single additive are used			
	Completely affixes patient-specific and auxiliary labels			
	Places completed PN in refrigeration prior to delivery			
	Multi-chamber PN Product			
	Identifies the correct product and volume to meet the PN order			
	Inspects the product for any damage or deterioration prior to removing the overwrap			
	Completely activates and agitates the product to mix all components together			
	Able to identify inappropriate additives			
	Makes manual additives as ordered			
	Completely affixes patient-specific and auxiliary labels			
	Places completed PN in refrigeration prior to delivery			
	Manual Compounding			
	Uses manual compounding technique when • Ingredient volume is too small for ACD to measure accurately • Interaction potential between ingredient and ACD component • Chemical reaction potential cannot be mitigated by altering sequence of addition, or • There is a shortage/outage of a PN component and conservation measures are in place			
	Requests independent pharmacist or supervisor verification for manually additives prior to adding to the PN			
	All PN Preparations			
	Environment for PN preparation complies with USP <797>			
	Verifies PN order • After initial order entry • Prior to injecting manual additive • After compounding			
	Visually inspects PN prior to dispensing			
	Reviews and compares PN order, patient-specific PN label, and compounding formulation prior to dispensing			
	Documents all steps as required for record keeping			

Reprinted from Boullata JI et al. Standardized competencies for parenteral nutrition order review and parenteral nutrition preparation, including compounding: the ASPEN model. *Nutr Clin Pract.* 2016; 31:548-55. With permission from ASPEN.

How many PN prescriptions do you revie in your typical shift?

a. None
b. 1 – 5
c. 6 – 12
d. > 12



Indications

PN Order Verification

- Patient name and other identifiers
- Birth date and/or age
- Allergies and associated manifestations
- Height and dosing weight (metric units)
- Diagnoses
- Indication(s)
- Administration route and vascular access device
- Date/time of order submission and administration
- Volume and rate of infusion

PN Order Form: Indications

Indications for PN

- ❑ Unable to obtain safe enteral access
- ❑ Failed trial of enteral nutrition
- ❑ Failed enteral access

- ❑ Bowel obstruction
- ❑ Paralytic ileus
- ❑ Incomplete resuscitation or hemodynamic instability
- ❑ Uncontrolled diarrhea
- ❑ High output fistula
- ❑ Intestinal failure, not otherwise specified

Consensus Recommendation

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American Society for Parenteral and Enteral Nutrition

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When Is Parenteral Nutrition Appropriate?

**Patricia Worthington, MSN, RN, CNSC[1]; Jane Balint, MD[2];
Matthew Bechtold, MD, FACP, FASGE, FACG, AGAF[3];
Angela Bingham, PharmD, BCPS, BCNSP, BCCCP[4];
Lingtak-Neander Chan, PharmD, BCNSP, CNSC, FACN[5]; Sharon Durfee, RPh, BCNSP[6];
Andrea K. Jevenn, RD, LD, CNSC[7]; Ainsley Malone, MS, RD, CNSC, FAND, FASPEN[8];
Maria Mascarenhas, MBBS[9]; Daniel T. Robinson, MD[10]; and Beverly Holcombe, PharmD, BCNSP , FASHP, FASPEN[11]**

Worthington P et al. *JPEN J Parenter Enteral Nutr.* 2017; 41:324-77.

Table 1. Elements of Appropriate PN Use.

• Identify clinical indications for PN, including manifestations of acute and chronic intestinal failure
• Recognize situations in which PN is not likely to be of benefit
• Initiate PN based on gastrointestinal function, nutrition status, and clinical status
• Select the vascular access device best suited to the therapy planned
• Implement measures to promote safety and reduce adverse outcomes
• Evaluate response to therapy
• Adjust in the therapeutic plan based on ongoing monitoring
• Assess continued need for PN
• Transition promptly to oral or enteral nutrition as feasible
• Collaborate across disciplines and departmental boundaries

PN, parenteral nutrition.

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Table 10.1. Common Indications for Home Parenteral Nutrition.[2,3,36]

• Short bowel syndrome
• Crohn's disease
• Intestinal motility disorders
• Chronic bowel obstruction due to benign adhesions or strictures
• Radiation enteritis
• Malabsorptive disorders
• Intestinal and pancreatic fistula
• Gastrointestinal malignancy
• Malignant bowel obstruction, carcinomatosis
• Complications of bariatric surgery
• Gastroschisis
• Long-segment Hirschsprung's disease

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Route and Timing

Route and Timing

- Route
  - Vascular access device
    - Central vein, preferred over peripheral vein
  - Dedicated lumen
    - Distal tip in superior vena cava near right atrial junction
- Timing of initiation
  - As soon as possible if malnourished
  - Within 3-5 days if at risk for malnutrition

Table 4.1. Clinical Conditions Warranting Cautious Initiation of Parenteral Nutrition in Adults.[52,53]

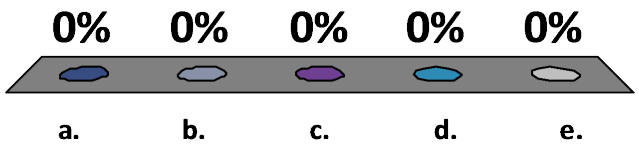
Conditions	Suggested Criteria
Hyperglycemia	Glucose greater than 180 mg/dL
Azotemia	Blood urea nitrogen greater than 100 mg/dL
Hypertriglyceridemia	Serum triglycerides greater than 200 mg/dL
Hyponatremia	Serum sodium less than 130 mEq/L
Hypernatremia	Serum sodium greater than 150 mEq/L
Hypokalemia	Serum potassium less than 3 mEq/L
Hypomagnesemia	Serum magnesium less than 1.3 mEq/L
Hypocalcemia	Ionized calcium less than 4.5 mg/dL
Hypophosphatemia	Serum phosphorus less than 2 mg/dL

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Dosing and Formulation

Which of the following represents the maximum recommended rate of IV lipid emulsion (ILE) infusion?

a. 4 mg/kg/min
b. 25 mg/kg/hr
c. 110 mg/kg/hr
d. 2 g/kg/day
e. I'm not sure



PN *Dosing* Review

- A dose for each nutrient “per day”
  - Macronutrient
    - Amino acids, dextrose, lipid
  - Micronutrient
    - Electrolytes, vitamins, trace elements
- Evaluate in context of clinical status
  - Indication
  - Body weight
  - Organ function
  - Concurrent medication (including previous PN order)

Energy Requirements

- **Requirements**
  - Predictive equations
  - Weight-based
  - Measured
- **Empiric values will vary depending on the patient**
  - BMI < 30 kg/m^2 → 25 kcal/kg/day
  - BMI 30-39.9 kg/m^2 → 15 kcal/kg/day
  - BMI ≥ 40 kg/m^2 → 10 kcal/kg/day

Energy Requirements

- Source
  - Carbohydrate and lipid are energy substrates
  - Amino acids are primarily an anabolic substrate
  - Net physiologic effect is dependent on absolute and relative amounts of each macronutrient

Approx IV Energy	Source	Max Dose	Max Infusion Rate
3.4 kcal/g	**Carbohydrate**	~5 g/kg/day	~3-4 mg/kg/min
10 kcal/g	**Lipid**	~1 g/kg/day	~110 mg/kg/hr

Protein Requirements

- **Requirements**
  - Weight-based
  - Measured
- **Empiric values will vary depending on the patient**
  - Maintenance ~1.0-1.5 g/kg/day
  - Repletion ~1.5-2.5 g/kg/day

Daily IV Micronutrient Dosing

Electrolytes

Na 1-2 mmol/kg		Mg 4-12 mmol
K 1-2 mmol/kg		Ca 5-7.5 mmol
Cl and Acetate		P 20-40 mmol

Vitamins

Retinol 1 mg	Thiamine 3-6 mg	Vitamin C 100-200 mg
Calciferol 5 μg	Riboflavin 3.6 mg	Pantothenic acid 15 mg
Tocopherol 10 mg	Niacin 40 mg	Biotin 60 μg
	Pyridoxine 4-6 mg	Cobalamin 5 μg
Phylloquinone 150 μg		Folate 400-600 μg

Trace Elements

Zn 3-4 mg	Cu 0.3-0.5 mg	Se 60-100 μg
Cr <12 μgMn 55 μg		

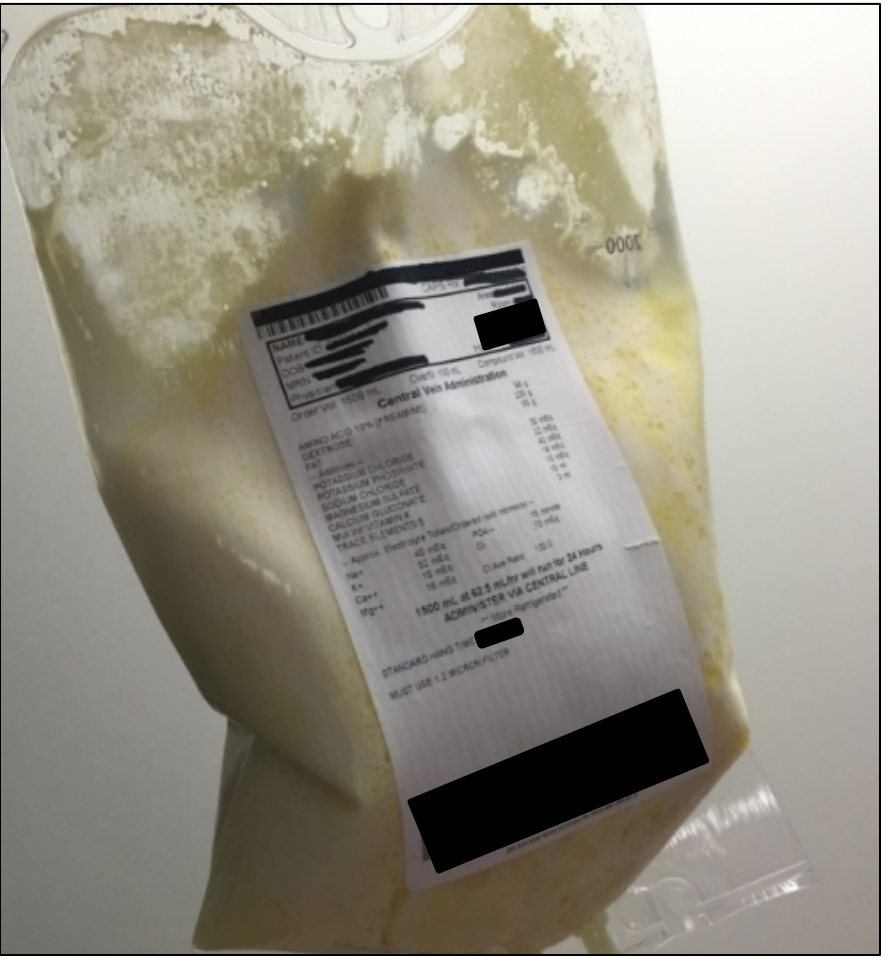
PN *Formulation* Review

- Osmolarity
  - Peripheral access limitation
- Compatibility
  - All ingredients (at ordered doses and PN volume)
- Stability
  - Of critical ingredients in admixture (at ordered doses and PN volume)
    - Lipid emulsion
    - Medication

Total Nutrient Admixture Formulation Limits

Macronutrient	Final Concentration
Amino acids	4 – 8%
Dextrose	> 10%
Lipid	2 – 5%

Micronutrient	Upper Limit Value
Ca (mEq/L) + PO_4 (mmol/L)	≤ 30
Ca (mEq/L) + Mg (mEq/L)	≤ 20
Na + K + Ca + Mg (mEq/L)	≤ 175
Zn (mg/L)	≤ 12



- Rarely is an unstable PN admixture actually *this* obvious to the naked eye
- Notice what appear to be free oil droplets throughout
  - If infused, these larger particles would eventually clog or rupture the filter, but not before many smaller particles are infused through the filter and obstruct capillaries with subsequent end-organ effects
- Thankfully not infused … but was ordered, reviewed, verified, and made!

Documentation

- Any identified problem with dosing or formulation
- Interventions to address dosing or formulation problem
- Document all steps as required for record keeping

Preparation

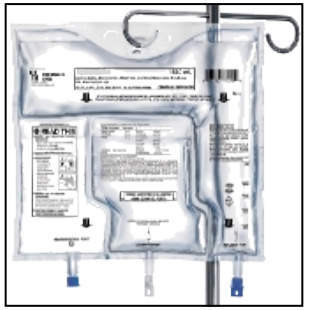
Compounded

Manufactured

Customized

Standardized

Standardized



2-in-1

3-in-1

Preparing the PN

- Compounding PN
  - Automated compounding device
    - Use vendor-validated initial set-up
    - Barcode technology to verify products
    - Trace tubing from each source container
- Activating multichambered PN product
  - Identify correct product and volume
    - Inspect for damage
    - Completely activate
    - Make necessary additions
- Manual additions
  - Independent verification

Products

- Multichambered PN product
  - Two chambers
  - Three chambers
- Macronutrients
  - Amino acids (AA) – ingredients are product-specific
  - IV lipid emulsions (ILE) – ingredients are product-specific

ILE Products

- First-generation
  - Cottonseed oil-based (e.g., Lipomul)†
- Second-generation
  - Soybean oil-based (e.g., Intralipid, Nutrilipid)
- Third-generation
  - Mixed oils
    - Medium chain-long chain triglycerides (MCT-LCT)‡
    - Soybean oil-olive oil (e.g., Clinolipid)‡
    - Soybean oil-MCTs-olive oil-fish oil (e.g., Smoflipid)
  - Modular oils
    - Fish oil (e.g., Omegaven)‡

†Removed from market.
‡Not yet available in the U.S.

Barriers to Successful PN Therapy

Address Barriers to Successful PN Therapy

- Administrative support
  - Integrated computerized provider order entry with clinical decision support
  - Policies, procedures, and practices based on available guidance documents
  - Training to complement or supplement knowledge and skills from pharmacy school and residencies
- Additional knowledge/skills support
  - ASHP, ASPEN, USP documents
  - ASPEN *(*www.nutritioncare.org*)*
    - *Nutrition Support Fundamentals* and *Nutrition Support Review Course*
    - Nutrition Self-Assessment program
    - *PN Safety* webinar series

Initiating and Managing Parenteral Nutrition Therapy: Clinical Case Studies

Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN,
and
Phil Ayers, Pharm.D., BCNSP, FASHP

Use of Parenteral Nutrition in an Acutely Ill Patient

Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN

Inpatient

60-year-old man with bicuspid AV with aortic stenosis and ascending aortic dilation, admitted for elective AVR and AAA repair

PMH – GERD, dysphagia, and recurrent diverticulitis (3 episodes in 9 mo)

PSH – cholecystectomy, inguinal hernia repair with mesh placement

AEH – aspartame → headache; lobster → hives

Meds at home – famotidine, fish oil capsules, aluminum hydroxide/magnesium carbonate, and ibuprofen prn

Inpatient: Hospital Course

Significant post-op events

- Day 1: GI bleed within hours, required resuscitation and embolization of left gastric artery
- Day 2: continued IV pantoprazole, epinephrine and phenylephrine, as well as propofol, hydromorphone, a β-blocker and antimicrobial regimen
- Day 3: NPO, extubated for 2nd time, hemodynamically stable, s/p VFSS SLP recommends standard aspiration precautions, regular diet with mechanical soft/chopped, small bites and sips
- Day 6: severe abdominal pain, fever, increased WBC, abdominal CT reveals multiple diverticular abscesses too small to drain, GI surgery recommends 'bowel rest' and an antimicrobial regimen
- Day 7: PN ordered for midline catheter administration

Inpatient: Nutrition Assessment on Day 7

History – poor oral intake (<75%) for several months, fatigue and weight loss with recurrent bouts of diverticulitis managed with NPO and antimicrobials

Vitals – 99°F 117/65 mmHg 78 bpm 18 bpm 75 kg and 1.75 m (BMI 24.5 kg/m^2)
Is/Os 1600/1850 mL (80 kg at admission, 90 kg 6-mo ago)

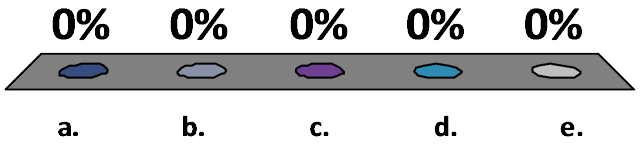
Physical – no abnormal lesions, abd soft but significant bilateral tenderness, peripheral muscle wasting, grip strength not tested but BIA → FM 22 kg (29%), FFM 53 kg (70%), total body water 53%, phase angle 5.9°

Labs –

Parameter	Na	K	Cl	CO_2	Ca	Mg	P	BUN	Cr	AST	ALT	AP	TB	INR	Gluc	Prealb	CRP	TG
Day 1	141	4.2	117	21	8.2	1.8	2.8	14	0.8	19	20	89	0.4	1.2	138	---	---	--
Day 3	139	4.0	110	20	--	--	--	18	1.1	--	--	--	--	--	126	---	---	--
Day 7	143	3.6	106	24	7.9	1.2	2.1	22	0.8	--	--	--	--	1.1	102	15	22	142

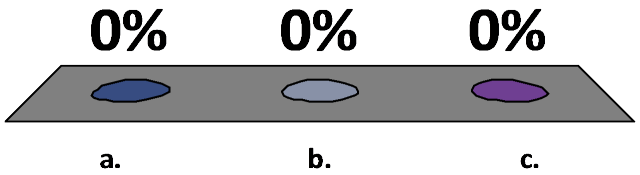
How would you describe this patient's nutrition status?

a. Well nourished
b. At risk for malnutrition
c. Moderate malnutrition
d. Severe malnutrition
e. I'm not sure



Does this patient have an indication for PN?

a. Yes
b. No
c. I’m not sure



Inpatient: PN Order (Day 7)

Amino acids (Plenamine)	100 g
Dextrose	100 g
ILE (Nutrilipid)	50 g

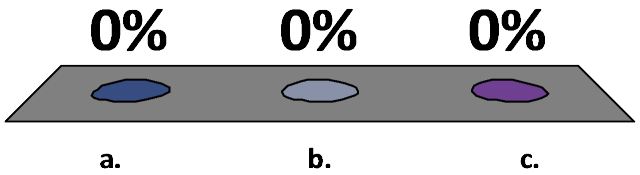
} 1160 kcal

NaCl	80 mmol
KCl	20 mmol
Ca gluc	5 mmol
Mg sulf	8 mmol
K phos	12 mmol

Multivitamins	10 mL
Multi-trace	3 mL
QS SWI	2000 mL

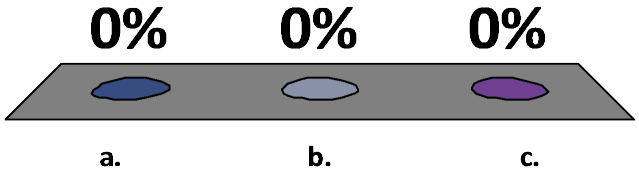
Is the PN order appropriate based on clinical dosing criteria?

a. Yes
b. No
c. I’m not sure



Is the PN order appropriate based on compatibility and stability criteria?

a. Yes
b. No
c. I’m not sure



Inpatient: PN Order Review (Day 7)

Clinical

- Amino acids 1.3 g/kg
- Dextrose 1.3 g/kg (~1 mg/kg/min)
- Lipid 0.7 g/kg (~30 mg/kg/hr)
- Energy 15.5 kcal/kg
- Fluid 27 mL/kg

Formulation

- Midline catheter is ‘peripheral’
  - Estimated osmolarity excessive
- Dextrose too low for TNA stability
- No micronutrient incompatibilities

	Dose	Volume	Final Conc
AAs (g)	100	666.7	5.0%
Dext (kcal)	340	143	5.0%
Fat (kcal)	500	250.0	2.5%
	Est mOsm/L	3221	954
	Plus SWFI	790	
	Total Volume	2000	

Inpatient: PN Order (Day 9)

Amino acids (Plenamine)	140 g	↑
Dextrose	210 g	↑
ILE (Nutrilipid)	60 g	↑

1765 kcal

NaCl/Na acet	80 / 30 mmol	
KCl	20 mmol	
Ca gluc	5 mmol	
Mg sulf	8 mmol	
K phos	28 mmol	↑

Multivitamins	10 mL	
Multi-trace	3 mL	
QS SWI	1600 mL	↓

Inpatient: PN Order Review (Day 9)

Clinical

- Amino acids 1.9 g/kg
- Dextrose 2.8 g/kg (~1.9 mg/kg/min)
- Lipid 0.8 g/kg (~33 mg/kg/hr)
- Energy 23.5 kcal/kg
- Fluid 21 mL/kg

	Dose	Volume	[Final]
Amino Acids (g)	140	933.33	8.6%
Dextrose (kcal)	715	300.42	12.9%
Fat Emulsion (kcal)	600	300.00	3.7%
		(assumes +250 mL of micronutrients)	
	Total (mL)	1633.75	

Step 1 Enter macronutrient doses
Step 2 See estimated total volume
Step 3 Check final concentr against rec ranges

Formulation

- PICC confirmed central
- Amino acids too high
  - Increase volume to 2000 mL
- No micronutrient incompatibilities

Case Review

- Patient with severe malnutrition requiring nutrition support intervention through the central venous route
- Pharmacist, dietitian, and prescriber worked together to provide a PN order that would be a stable admixture through a central vein
- Patient received goal PN for 7 days before transitioning to a regular diet

Use of Parenteral Nutrition in Patient with Enterocutaneous Fistula (ECF)

Phil Ayers, Pharm.D., BCNSP, FASHP

Case Study

LH 37-year-old woman with ECF on home PN (HPN). Patient is currently receiving chemotherapy with plans for surgical repair of ECF January 2018.

62 inches (157.5 cm), 46 kg, BMI 18.5 k/m^2

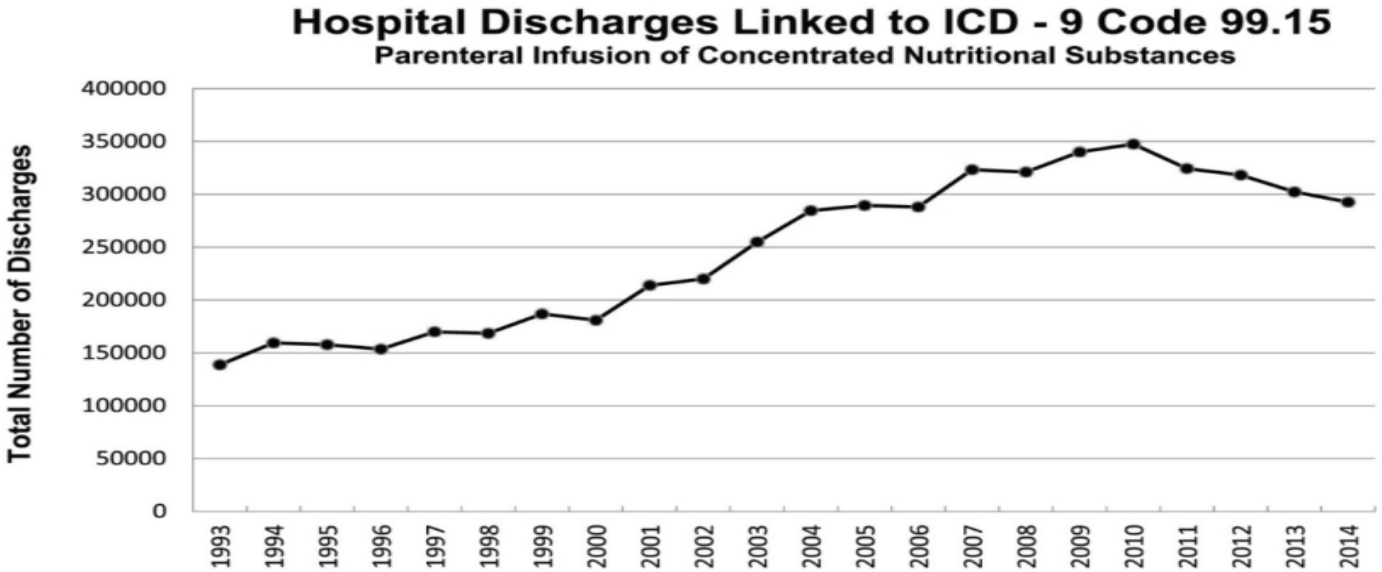
PMH: peritoneal carcinoma, multiple sclerosis

PSH: colon resection, small bowel resection, ileostomy, hysterectomy

Case Study

10/18 – PN day 161 providing 1.9 g/kg/day protein, 32 kcal/kg/day, and 52 mL/kg/day

Weekly comprehensive metabolic panel, magnesium, phosphorus, triglycerides, prealbumin, complete blood count with differential



Total number of hospital discharges with *ICD-9* code of 99.15, parenteral nutrition, 1993–2014. Data from National Inpatient Sample of HCUP from AHRQ. http://hcupnet.ahrq.gov/. Accessed Nov 22, 2016.

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Table 2. Medicare Criteria for HPN.[7]

A. Massive small bowel resection within 3 mo of initiating HPN
HPN therapy needed >90 d
≤5 ft (153 cm) of small bowel distal to the ligament of Treitz

B. Short bowel syndrome
HPN therapy needed >90 d,
Enteral intake of 2.5–3 L,
Enteral losses exceed 50% of enteral intake, and
Urine output is <1 L per 24 h

C. Bowel rest for at least 3 mo
HPN therapy needed >90 d,
Symptomatic pancreatitis with/without pseudocyst,
Severe exacerbation of regional enteritis, or
Proximal enterocutaneous fistula where distal enteral tube feeding is not possible

D. Complete mechanical small bowel obstruction
HPN therapy needed >90 d
Inoperable

E. Malabsorption and malnutrition
HPN therapy needed >90 d
10% weight loss over ≤3 mo
Serum albumin ≤3.4 g/dL
Severe fat malabsorption
- Standard 72-h fecal fat test
- Fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 g/d of fat

F. Severe motility disorder (of small intestine and/or stomach) and malnutrition
HPN therapy needed >90 d
10% weight loss over ≤3 mo
Serum albumin ≤3.4 g/dL
Unresponsive to max doses of prokinetic medication (presence of daily nausea/vomiting)
Motility disorder demonstrated via
- Solid meal gastric emptying study or barium/radiopaque pellets that do not reach the right colon by 6 h

G/H: Above condition with malnutrition and failed enteral tube feeding trial
10% weight loss within 3 mo + serum albumin ≤3.4 g/dL + failed tube feeding trial + > 90 d HPN + 1 condition below:
- Moderate fat malabsorption (fecal fat >25% of enteral intake on a diet of 50 g/d of fat measured with a 72-h fecal fat test)
- Malabsorption as confirmed by Sudan stain or d-xylose stool test
- Gastroparesis as described in scenario F where isotope or pellets fail to reach the jejunum in 3–6 h, manometric motility studies with results consistent with abnormal gastric emptying, unresponsive to prokinetic medication
- Small bowel dysmotility with gastric to right colon transit between 3 and 6 h, unresponsive to prokinetic medication
- Small bowel resection leaving >5 ft of small bowel beyond the ligament of Treitz
- Short bowel syndrome not as severe as scenario B
- Mild to moderate exacerbation of regional enteritis or enterocutaneous fistula
- Partial mechanical small bowel obstruction and surgery is not an option

HPN, home parenteral nutrition.

Reprinted from Kirby DF, Corrigan ML, Hendrickson E et al. Overview of home parenteral nutrition: an update. *Nutr Clin Pract*. 2017 Oct 1. [Epub ahead of print]. With permission from ASPEN.

Table 10.1. Common Indications for Home Parenteral Nutrition.[2,3,36]

• Short bowel syndrome
• Crohn's disease
• Intestinal motility disorders
• Chronic bowel obstruction due to benign adhesions or strictures
• Radiation enteritis
• Malabsorptive disorders
• Intestinal and pancreatic fistula
• Gastrointestinal malignancy
• Malignant bowel obstruction, carcinomatosis
• Complications of bariatric surgery
• Gastroschisis
• Long-segment Hirschsprung's disease

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Table 4.1. Clinical Conditions Warranting Cautious Initiation of Parenteral Nutrition in Adults.[52,53]

Conditions	Suggested Criteria
Hyperglycemia	Glucose greater than 180 mg/dL
Azotemia	Blood urea nitrogen greater than 100 mg/dL
Hypertriglyceridemia	Serum triglycerides greater than 200 mg/dL
Hyponatremia	Serum sodium less than 130 mEq/L
Hypernatremia	Serum sodium greater than 150 mEq/L
Hypokalemia	Serum potassium less than 3 mEq/L
Hypomagnesemia	Serum magnesium less than 1.3 mEq/L
Hypocalcemia	Ionized calcium less than 4.5 mg/dL
Hypophosphatemia	Serum phosphorus less than 2 mg/dL

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

ASPEN-FELANPE Clinical Guidelines: Nutrition Support of Adult Patients with Enterocutaneous Fistula (ECF)

- Published in *Journal of Parenteral and Enteral Nutrition* (*JPEN*) in January 2017
- GRADE process
- 7 Questions addressed in the guidelines with quality of evidence

Kumpf VJ et al. *JPEN J Parenter Enteral Nutr*. 2017; 41:104-12.

ASPEN-FELANPE Clinical Guidelines: Nutrition Support of Adult Patients with Enterocutaneous Fistula (ECF)

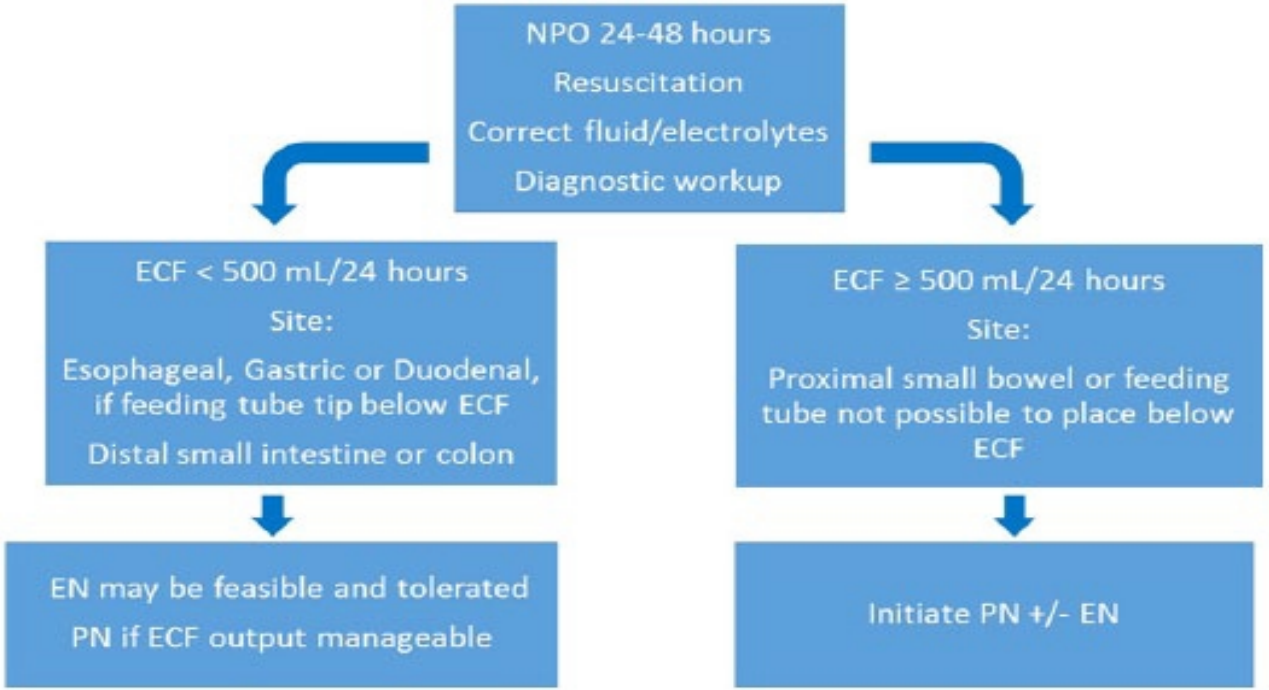
1. What factors best describe nutrition status?
2. What is the preferred route of nutrition support?
3. What protein and energy intake provide best clinical outcomes?
4. Is fistuloclysis associated with better outcomes than standard care?
5. Are immune-enhancing formulas associated with better outcomes than standard formulas?
6. Does the use of somatostatin or somatostatin analogue provide better outcomes?
7. When is home parenteral nutrition support indicated?

Kumpf VJ et al. *JPEN J Parenter Enteral Nutr*. 2017; 41:104-12.

What is the preferred route of nutrition support?

Quality of Evidence: Very low

Routes of Nutrition Therapy in ECF Patients



Kumpf VJ et al. *JPEN J Parenter Enteral Nutr*. 2017; 41:104-12.

When is home parenteral nutrition support indicated?

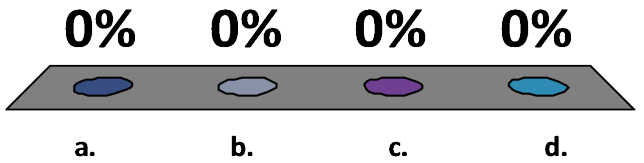
Quality of evidence: Based on Consensus

- Patient is medically stable
- Fistula output is manageable
- High-output (>500 mL/24 hr) when surgical repair is not yet advised
- Sustain National Patient Registry for Nutrition Care: Adult HPN indication for ECF-19%

Kumpf VJ et al. *JPEN J Parenter Enteral Nutr*. 2017; 41:104-12.

A patient with an enteroatmospheric fistula with high output may require up to _____ protein.

a. 0.8 g/kg/day
b. 1 g/kg/day
c. 1.5 g/kg/day
d. 2.5 g/kg/day



What protein and energy intake provide best clinical outcomes?

Quality of Evidence: Consensus only

- Protein 1.5-2 g/kg/day
  - Up to 2.5 g/kg/day in patients with enteroatmospheric fistula and high fistula output
- Energy intake appropriate to the patient's energy requirements based on results of nutrition assessment (observational studies report 25-30 kcal/kg/day)

Kumpf VJ et al. *JPEN J Parenter Enteral Nutr*. 2017; 41:104-12.

Table 13.2. Laboratory Monitoring During PN (Adult and Pediatric).[1,10,17,19]

	Acute Care PN			Long-Term PN			
Parameter	Baseline	Days 1–7	Ongoing, Stable	Initial, Postdischarge	Weeks 1–4 (or Until Stable)	At 3 mo	Ongoing, Stable
Glucose, BUN, creatinine, electrolytes, calcium, magnesium, phosphorus	✓	Daily × 3 or until stable	1–2×/wk or as clinically indicated	✓	✓		Monthly
CBC with differential	✓	Daily × 3 or until stable	1–2×/wk	✓	✓		Monthly
Total bilirubin, direct bilirubin, AP, AST, ALT,	✓		Weekly	✓			Monthly
PTT, PT, INR	✓		Weekly				Monthly
Triglyceride level	✓	Pediatric: daily until stable then weekly	Weekly	✓			Monthly
Serum proteins (to monitor inflammation)	✓		Weekly	✓			Monthly
Iron indices			As clinically indicated			✓	Every 3–6 mo
Zinc, selenium, manganese, copper, chromium			As clinically indicated			✓	Every 3–6 mo
Vitamin A, 25-OH vitamin D, vitamin E			As clinically indicated			✓	Every 12 mo
Vitamin B_{12} and folate			As clinically indicated			✓	Every 6–12 mo
TSH				As indicated			Every 12 mo
Carnitine			No guideline for adults			✓ Pediatric patients	Every 3–12 mo

ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; CBC, complete blood count; INR, international normalized ratio; PN, parenteral nutrition; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone.

Reprinted from Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77. With permission from ASPEN.

Home PN

LH PN Order (Day 161)

Amino acids (Travasol)	87 g
Dextrose (70%)	189 g
ILE (Smoflipid)	50 g
NaCl	180 mEq
KCl	30 mEq
K acetate	30 mEq
Ca gluc	5 mEq
Mg sulf	16 mEq
K phos	10 mmol
Multivitamins	10 mL
Multi-trace (conc)	1 mL
Folic acid	1 mg
QS SWI	2400 mL

Table 1. Evaluation of Fluid Balance.

Type of Parameter	Assessment Type	Sign or Symptom of Dehydration	Sign or Symptom of Fluid Overload
Subjective or physical symptom	Patient reported	• Dry mouth • Excessive thirst • Dark-colored urine • Dizziness • Headache • Cramping in extremities • Dry skin • Poor skin turgor	• Shortness of breath • Tachypnea • Edema
Objective sign	Intake and output documentation	• ≥2 kg weight loss in 48 hours • Negative fluid balance (O > I for 48 hours) • <1 L urine output in 24 hours • Increased GI losses from baseline	• ≥2 kg weight loss in 48 hours • Positive fluid balance (I > O by 1 L for 2 consecutive days) • Decreased GI losses from baseline
	Laboratory values	Levels increase: • Chloride • Serum urea nitrogen • Creatinine Levels may increase or decrease: • Sodium	Levels decrease: • Sodium • Chloride • Creatinine • Albumin
	Vital signs	• Tachycardia • Hypotension, specifically orthostatic	• Hypertension

GI, gastrointestinal; I, input; O, output.

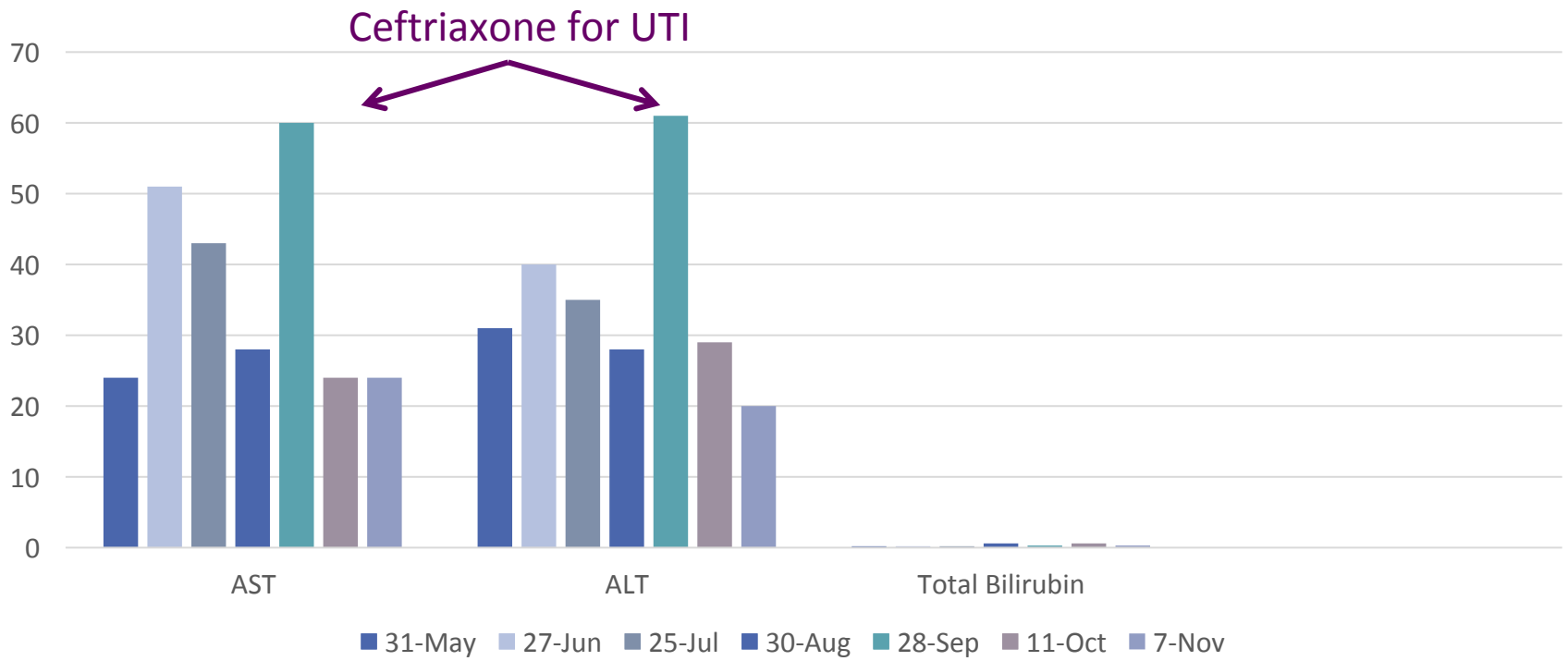
Reprinted from Davila J, Konrad D. Metabolic complications of home parenteral nutrition. *Nutr Clin Pract*. 2017 Oct 1. [Epub ahead of print]. With permission from ASPEN.

Four-Week PN with Soybean Oil, Medium Chain Triglycerides, Olive Oil, and Fish Oil (SMOF) vs. Soybean Oil (SO) Emulsion in Patients with Intestinal Failure

- Double-blind, multicenter, randomized controlled trial
- 73 patients (n = 34 in SMOF group and n = 39 in SO group)
- PN similar: 1.3 g/kg/day IVFE, 3 g/kg/day dextrose, and 1.2 g/kg/day protein
- After 4 weeks, mean concentrations of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin significantly lower in SMOF group vs. SO group

Klek S et al. *Clin Nutr.* 2013; 32:224-31.

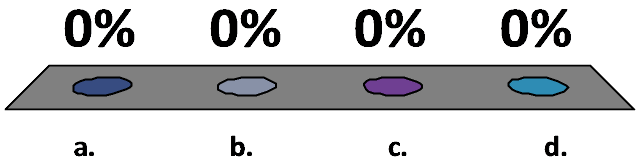
LH May-November: AST/ALT/Total Bilirubin



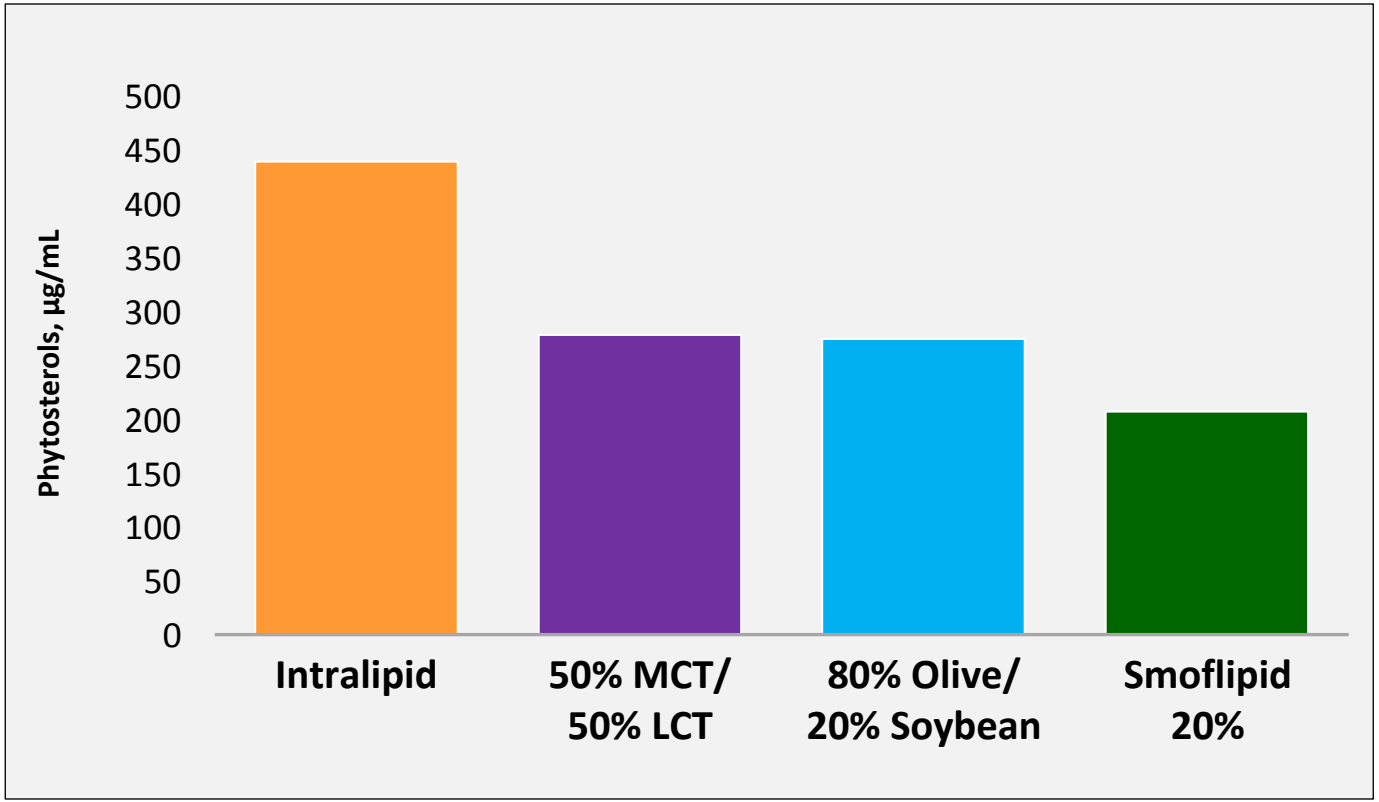
UTI = urinary tract infection

Which ILE has the lowest content of phytosterol?

a. Clinolipid
b. Intralipid
c. Nutrilipid
d. Smoflipid



ILE and Phytosterol Content



Xu Z et al. *Nutrients*. 2012; 4:904-21.

Case Review:
Considerations for the Home PN Candidate

- Appropriate candidate
- Hemodynamically stable
- Competent
- Monitor for complications

Key Takeaways

- Visceral proteins are not the gold standard for the diagnosis of malnutrition
- Competent pharmacists review every PN order
- Competent pharmacist-pharmacy technician team prepare every PN admixture
- Patient should be metabolically stable before discharging on home parenteral nutrition therapy
- P&Ps and practices reflect available best practices

What will you do as a follow-up to today's program?

(Select all that apply)

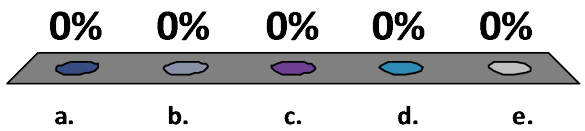
a. Interpret serum albumin and prealbumin with caution

b. Assess nutrition status before recommending PN therapy

c. Review all PN regimens against dosing & formulation guidelines

d. Revisit PN preparation steps to align with best practices

e. Revise P&P to align with current best practices



Selected Resources

- Ayers P, Adams S, Boullata J et al. A.S.P.E.N. parenteral nutrition safety consensus recommendations. *JPEN J Parenter Enteral Nutr*. 2014; 38:296-333.
- Boullata JI, Gilbert K, Sacks G et al. A.S.P.E.N. clinical guidelines: parenteral nutrition ordering, order review, compounding, labeling, and dispensing. *JPEN J Parenter Enteral Nutr*. 2014; 38:334-77.
- Boullata JI, Holcomb B, Sacks G et al. Standardized competencies for parenteral nutrition order review and parenteral nutrition preparation, including compounding: the ASPEN model. *Nutr Clin Pract*. 2016; 31:548-55.
- Ensuring the Safe Use of Parenteral Nutrition → www.pnsafeuse.org

Selected Resources (cont.)

- Guenter P, Boullata JI, Ayers P et al. Standardized competencies for parenteral nutrition prescribing: the ASPEN model. *Nutr Clin Pract*. 2015; 30:570-6.
- Mundi MS, Nystrom EM, Hurley DL, McMahon MM. Management of parenteral nutrition in hospitalized patients. *JPEN J Parenter Enteral Nutr*. 2017; 41:535-49.
- Worthington P, Balint J, Bechtold M et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr*. 2017; 41:324-77.

Faculty Discussion and Questions

- Orlando Audience
  - P R I N T your questions on a question card and a staff monitor will pick it up **OR**
  - Proceed to nearest microphone to ask your question
- Webinar audience
  - Expand control panel (click on orange arrow) and type in your question